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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,098	04/16/2004	Ma. Teresa Y. Tan	1278-007 (DIZ-5)	9265

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BROWN & MICHAELS, PC
400 M & T BANK BUILDING
118 NORTH TIOGA ST
ITHACA, NY 14850

EXAMINER	
COTTON, ABIGAIL MANDA	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/826,098	TAN ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/16/2004,7/6/2004 and 12/22/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/16/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-14 are pending in the application.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the Philippines on June 6, 2003. It is noted, however, that applicant has not filed a certified copy of the Philippines 12003000285 application as required by 35 U.S.C. 119(b), and thus the requirements for claiming foreign priority have not been satisfied.

Claim Objections

Claim 9 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer in the alternative only to the claims from which it depends. See MPEP § 608.01(n). A proper form for such a multiple dependent claim may be, for example, "the composition according to claim 6, 7 or 8." Appropriate correction is required.

Claim 9 is being interpreted as depending in the alternative from claim 6, 7 or 8 for the purposes of applying art in the present action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,897,270 to Deutsch et al, issued January 30, 1990, in view of U.S. Patent No. 6,080,426 to Amey et al, issued on June 27, 2000.

Deutsch et al. teaches providing a pharmaceutical tablet of cefuroxime axetil, and teaches the desirability of providing a film coat on the tablet to mask the bitter taste of the antibiotic (see abstract, in particular.)

Regarding claims 6-8, Deutsch et al. furthermore teaches that the tablet can contain from 2 to 15% by weight of disintegrant, and that an effective amount of disintegrant can be provided to achieve the desired disintegration of the tablet after rupture of the film (see column 3, lines 65-68 and column 2, line 63 through column 3, line 2, in particular.)

Regarding claim 9, Deutsche et al. teaches that the disintegrant can be potato starch, sodium starch glycolate, croscarmellose sodium and other (see column 3, lines 56-65, in particular.) Regarding claim 4, Deutsch et al. teaches that the cefuroxime axetil is desirably in the amorphous form (see column 4, lines 52-55, in particular.)

Deutsch et al. ~~also~~ does not teach providing the specific % weight ranges of disintegrant in the caplet as recited in claims 6-8. However, Deutsch et al. teaches providing a range of disintegrant that ~~is~~ overlaps with the range recited in claim 6, and that is very close to the ranges recited in claims 7-8, with the range recited in claim 7 having a lower limit (20%) that is only 5% greater than the preferred upper limit (15%) specified by Deutsch. Deutsch et al furthermore teaches of the desirability of providing an effective amount of disintegrant in the tablet to disintegrate the tablet immediately upon rupture of the film coating. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to optimize the % weight of disintegrant included in the tablet to provide the desired rate of disintegration of the tablet. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Deutsch et al. does not specifically teach providing the tablet in a capsule or the composition of the capsule.

Amey et al. teaches a process for encapsulation of caplets in a capsule comprising providing empty capsule parts, filling at least one of said capsule parts with one or more caplets, putting said capsule parts together, and treating the combined parts by cold shrinking (see abstract, in particular.) Amey et al. teaches that capsules are desirable because they are generally easy to swallow, and also because they provide a neutral taste instead of the bitter taste of many pharmaceutical substances in caplets (see column 1, lines 16-28, in particular.)

Regarding claims 3-5, Amey et al. teaches that a specifically preferred version has a clearance of the capsule shell and caplet in the range of from about 0 to about -0.5 mm, meaning that the caplet is compressed in the capsule (see column 2, lines 50-54, in particular.) Thus, as Amey et al. teaches a caplet and capsule have less than zero clearance between each other, it follows that the diameter of the caplet taught by Amey et al. must be greater than or equal to 80% of the internal diameter of the capsule taught by Amey et al.

Regarding claims 11-12 and 14, Amey et al. teaches that suitable materials for the capsule can include gelatin, hydroxypropyl methylcellulose or starch (a polysaccharide.) See column 3, lines 18-34, in particular.

Accordingly, it would have been obvious to one of ordinary skill in the art to provide capsule taught by Amey et al. to encapsulate the cefuroxime axetil tablet taught

by Deutsch et al, because Deutsch et al. teaches the desirability of masking the bitter taste of such a tablet, and Amey et al. teaches that encapsulating a tablet (caplet) in a capsule is a suitable means of providing a neutral taste for an otherwise bitter pharmaceutical substance. Thus, one of ordinary skill in the art would have been motivated to provide the cefuroxime axetil tablet of Deutsch et al. in the capsule of Amey et al, with the expectation of providing a suitable dosage form having a neutral, non-bitter taste, as well as other benefits such as easy swallowability.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,897,270 to Deutsch et al, issued January 30, 1990, in view of U.S. Patent No. 6,080,426 to Amey et al, issued on June 27, 2000, as applied to claims 1-12 and 14 above, and further in view of U.S. Patent No. 6,482,432 to Xiping Wang, issued November 19, 2002.

Deutsch et al. and Amey et al. are applied as discussed above, and teach providing a cefuroxime axetil tablet inside a capsule. Deutsch et al. and Amey et al. do not specifically teach that the capsule is made of vegetable or plant-based cellulose.

Wang teaches that there is consumer demand for capsules made from vegetable sources, such as vegetable gelatin or hydroxypropyl methylcellulose (see column 1, lines 52-60, in particular.) Wang also provides examples of therapeutic ingredients

being encapsulated in cellulose derivative capsules or vegetable cellulose capsules (see column 2, lines 55-61, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have been motivated to provide a capsule made of vegetable based cellulose in the encapsulated caplet dosage form of Deutsch et al. and Amey et al, with the expectation of providing a capsule that is suitable for encapsulating therapeutic ingredients and that is in demand by consumers.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 8:30-5:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER